



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donald L. Wise, Debra J. Trantolo, David D. Hile, and Stephen A. Doherty

Serial No.: 10/613,975 Art Unit: 1642

Filed: July 3, 2003 Examiner: Not Yet Assigned

For: ***VACCINES TO INDUCE MUCOSAL IMMUNITY***

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eight (8) pages of Form PTO-1449 and copies of the sixty-eight documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
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5,456,917	10-10-1995	Wise, et al.	424/426

### Publications

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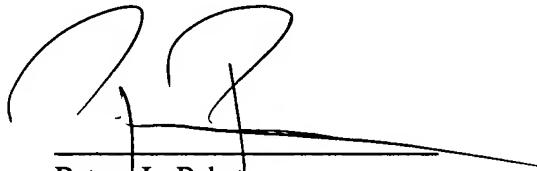
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**Remarks**

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Dated: October 28, 2003

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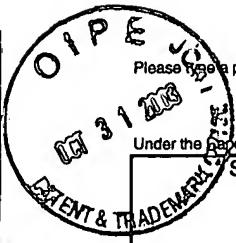
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (use as many sheets as necessary)		Complet If Known
		Application Number 10/613,975
		Filing Date July 3, 2003
		First Named Inventor Donald L. Wise
		Group Art Unit 1642
		Examiner Name Attorney Docket Number CSI 130
Sheet	1	of
		8

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

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		Filing Date	July 3, 2003
		First Named Inventor	Donald L. Wise
		Group Art Unit	1642
		Examiner Name	
Sheet	2	of	8
		Attorney Docket Number	CSI 130

**OTHER ART – NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," <i>Pharm. Res.</i> 10(7): 945-953 (1993).	
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Application Number</b> 10/613,975	
		<b>Filing Date</b> July 3, 2003	
		<b>First Named Inventor</b> Donald L. Wise	
		<b>Group Art Unit</b> 1642	
		<b>Examiner Name</b>	
Sheet	5	of	8
		<b>Attorney Docket Number</b> CSI 130	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci., USA</i> 89: 10277-10281 (1992).	
		KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," <i>Infect. Immunol.</i> 67: 5658-5663 (1999).	
		KRIEG, et al., "CpG DNA induces sustained 1L-12 expression in vivo and resistance to <i>Listeria monocytogenes</i> challenge," <i>J. Immunol.</i> 161: 2428-2434 (1998).	
		KUPER, et al., "The role of nasopharyngeal lymphoid tissue," <i>Immunol. Today</i> 13(6): 219-224 (1992).	
		LABHASETWAR, et al., "A DNA controlled-release coating for gene transfer: transfection in skeletal and cardiac muscle," <i>J. Pharm. Science</i> 87(11): 1347-1350 (1998).	
		LEE, et al., "Safety, tolerability and humoral immune responses after intramuscular administration of a malaria DNA vaccine to healthy adult volunteers," <i>Vaccine</i> 18: 1893-1901 (2000).	
		LEE, et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with <i>Helicobacter pylori</i> ," <i>Vaccine</i> 17: 3072-3082 (1999).	
		LEPPLA, et al., "Proteolytic activation of anthrax toxin bound to cellular receptors," in <i>Bacterial protein toxins</i> (Fehrenbach, et al., eds) pp. 111-112, Gustav Fischer: New York (1988).	
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		LITTLE & KNUDSON, "Comparative efficacy of <i>Bacillus anthracis</i> live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," <i>Infect. Immun.</i> 52(2): 509-512 (1986).	

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Sheet

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of

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Application Number	10/613,975
Filing Date	July 3, 2003
First Named Inventor	Donald L. Wise
Group Art Unit	1642
Examiner Name	
Attorney Docket Number	CSI 130

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		LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug. Target.</i> 8(1): 39-50 (2000).	
		LUO, et al., "Synthetic DNA delivery systems," <i>Nature Biotech</i> 18: 33-37 (2000).	
		MCGHEE, et al., "The mucosal immune system: from fundamental concepts to vaccine development," <i>Vaccine</i> 10(2): 75-88 (1992).	
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		MILNE, et al., "Anthrax protective antigen forms oligomers during intoxication of mammalian cells," <i>J. Biol. Chem</i> 269(32): 20607-20612 (1994).	
		NEUTRA, et al., "Antigen sampling across epithelial barriers and induction of mucosal immune responses," <i>Ann. Rev. Immunol.</i> 14: 275-300 (1996).	
		O'HAGAN, et al., "Controlled release microparticles for vaccine development," <i>Vaccine</i> 9: 768-771 (1991).	
		O'HAGAN, et al., "Long-term antibody response in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," <i>Vaccine</i> 11(9): 965-969 (1993).	
		PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," <i>J. Imm. Meth.</i> 195: 135-138 (1996).	
		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," <i>J. Control. Rel.</i> 75: 211-224 (2001).	

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		Filing Date <b>July 3, 2003</b>	First Named Inventor <b>Donald L. Wise</b>
		Group Art Unit <b>1642</b>	Examiner Name
Sheet <b>7</b>	of <b>8</b>	Attorney Docket Number <b>CSI 130</b>	

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		PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," <i>Vaccine</i> 13(15): 1427-1430 (1995).	
		PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infect. Immunity</i> . 69(7): 4509-4515 (2001).	
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		SINGH, et al., "Controlled delivery of diphtheria toxoid using biodegradable poly(D,L-lactide) microcapsules," <i>Pharm. Res.</i> 8: 958-961 (1991).	
		SMITH, et al., "Induction of secretory immunity with bioadhesive poly (D,L-lactid-co-glycolide) microparticles containing <i>Streptococcus sobrinus</i> glucosyltransferase," <i>Oral. Microbiol. Immunol.</i> 15: 124-130 (2000).	
		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against <i>Plasmodium falciparum</i> malaria," <i>N. Engl. J. Med.</i> 336: 86-91 (1997).	
		THOMASIN, et al., "Tetanus toxoid and synthetic malaria antigen containing poly(lactide)/poly(lactide-co-glycolide) microspheres: importance of polymer degradation and antigen release for immune response," <i>J. Control. Rel.</i> 41: 131-145 (1996).	
		TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," <i>J. Control. Rel.</i> 66: 229-241 (2000).	
		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," <i>Proc. 5<sup>th</sup> World Congress, Chem. Eng.</i> (1996).	

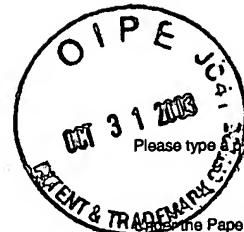
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		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," <i>J. Biomed. Mat. Res.</i> 19: 349-365 (1985).	
		WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four <i>Plasmodium falciparum</i> DNA plasmids," <i>Infect. Immunity</i> . 66(9): 4193-4202 (1998).	
		WEINER, "Oral tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 91: 10762-10765 (1994).	
		WOLFF, et al., "Direct gene transfer into mouse muscle in vivo," <i>Science</i> 247: 1465-1468 (1990).	
		WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," <i>Immuno. Res.</i> 16(2): 187-201 (1997).	
		YEE, et al., "Loss of either CD4 <sup>+</sup> or CD8 <sup>+</sup> cells does not affect the magnitude of protective immunity to an intracellular pathogen, <i>Fancisella tularensis</i> strain LVS," <i>J. Immunol.</i> 157: 5042-5048 (1996).	

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